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FEB 0 4 2002

NxStage Medical, Inc.
Dialysate Concentrate
510(k) Premarket Notification

Section VI: Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	439 South Union Street, Suite 501 Lawrence, MA 01843
Phone:	1-978-687-4700
Fax:	(978) 687-4800
Contact Person:	Karen St. Onge, Director, Quality Assurance/Regulatory Affairs
Date of Preparation:	1 February 2002

B. Device Name:

Trade Name:	NxStage Dialysate Concentrate
Common/Usual Name:	Dialysate Concentrate for Hemodialysis (Liquid or Powder)
Classification Name:	Dialysate Concentrate for Hemodialysis (Liquid or Powder)

C. Predicate Device Name:

The predicate devices for the NxStage Dialysate Concentrate are:

- NormoCarb Sterile Bicarbonate Concentrate (#K001059, 6/30/2000);
- Baxter Premixed Dialysate for Hemodiafiltration (#K910270, 4/18/1991).

D. Device Description/Indications for Use:

NxStage Dialysate Concentrate is a clear, sterile, non-pyrogenic concentrate, provided in 150 ml unit-dose vials, which, when diluted with sterile water in the required proportions, creates a dialysate for use in renal replacement therapy. When diluted, NxStage Dialysate Concentrate yields a dialysate with the following composition:

- Sodium - 140.0 mEq/L;
- Calcium - 3.0 mEq/L;
- Potassium - 2.0 mEq/L;
- Magnesium - 1.0 mEq/L;
- Chloride - 111.0 mEq/L;
- L-Lactate - 35.0 mEq/L.

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Intended Use

NxStage Dialysate Concentrate, after dilution, is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. Is the product a device?

YES – NxStage Dialysate Concentrate is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the NxStage Dialysate Concentrate is equivalent to those for the predicate dialysis concentrates.

NxStage Dialysate Concentrate
NxStage Dialysate Concentrate, after dilution, is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

NormoCarb Sterile Bicarbonate Concentrate (#K001059)
Normocarb, after dilution, is indicated for use in Continuous Renal Replacement Therapy (CRRT).

Baxter Premixed Dialysate for Hemodiafiltration (#K910270)
Baxter Premixed Dialysate is indicated for acute dialysis modalities such as continuous arteriovenous hemodiafiltration (CAVHD), and continuous venous-venous hemodiafiltration (CVVHD), when treating acute renal failure patients with hypervolemia and uremia that requires high solute clearance.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The composition of the NxStage Dialysate Concentrate is equivalent to that of other commercially available hemodialysis concentrates and raises no new types of safety or effectiveness questions. In addition, the packaging, sterility status and method of preparation are equivalent to those of the NormoCarb Sterile Bicarbonate Concentrate.

Section VI: Summary of Safety and Effectiveness

4. Does descriptive or performance information demonstrate equivalence?

YES – NxStage Medical, Inc. believes that the information provided in this submission clearly describes the NxStage Dialysate Concentrate and demonstrates that it is substantially equivalent to other commercially available hemodialysis concentrates.

F. Safety Summary

Both the vial label and Instructions for Use include indications for use, cautions and warnings, as well as the general operating instructions required for proper use of NxStage Dialysate Concentrate. In addition, "Medication Added" labels are provided for customer use. This information promotes safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Ms. Karen St. Onge
Director, Quality Assurance
NxSTAGE Medical, Inc.
439 S. Union St., 5th Floor
LAWRENCE MA 01843

Re: K013655
Trade/Device Name: NxStage Dialysate Concentrate
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: November 2, 2001
Received: November 6, 2001

Dear Ms. St. Onge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013655

Device Name: NxStage Dialysate Concentrate

Indications for Use: NxStage Dialysate Concentrate, after dilution, is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013655